

Notice of Allowability

Application No.

10/024,450

Examiner

Jeanine A Goldberg

Applicant(s)

HUANG ET AL.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/20/04.
2. ☒ The allowed claim(s) is/are 17-23.
3. ☒ The drawings filed on 13 September 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.


JEANINE A. GOLDBERG
PATENT EXAMINER

DETAILED ACTION

1. This action is in response to the after final amendment and response filed December 20, 2004.
2. Claims 17-23 are allowable.

REASONS FOR ALLOWANCE

3. The following is an examiner's statement of reasons for allowance.

The claims have been amended to specify the type of tumor and the positions of the poly(A) tracts. The claims remain drawn to "abnormal number of adenosine nucleotides in RIZ poly(A).ⁿ" Upon review of the specification and the sequence listing, frameshifts in either of the two poly(A) tracts of the RIZ gene were detected in high percentage of MSI(+) tumor cells (page 17). RIZ poly(A) tract mutations were not detected in MSI- tumor cells and cell lines.

The response filed December 20, 2004 argues that frameshift mutations in either tract, caused by an addition or deletion of an A residue, are predicted to lead to loss of the C-terminal domain of the RIZ protein that is involved in PR binding (page 6 of response, page 18, lines 16-19 of specification). For the poly(A) tract from 4393-4400 of SEQ ID NO: 3, a deletion of one adenosine produces a stop codon two residues from the tract and a mutant protein lacking the C-terminal 293 amino acids (page 32, lines 20-25). For a deletion of two adenosine, a stop codon is produced about 20 amino acids down stream.

For the poly(A) tract from 4582-4590 of SEQ ID NO: 3, a frameshift caused by a deletion of one adenosine is expected to cause the fusion of truncated RIZ1 and RIZ2 lacking the C-terminal 219aa with a novel reading from of 76aa (page 27, lines 18-25). A frameshift occurs with the deletion of two adenosines also.

An insertion of one adenosine would cause a similar frameshift as a deletion of two adenosines, and a corresponding truncation. Similarly an insertion of two adenosines would cause a similar frameshift as a deletion of a single adenosine and a corresponding truncation.

The specification illustrates various tumors that have deletions of one or two adenosine within the poly(A) tracts of the instant claims. Each of these are located within MSI+ tumors. The abnormal number of adenosine nucleotides which include deletions of one or two adenosine would result in the same frameshift type mutations for insertion of one or two adenosines, for example. The specification clearly illustrates that frameshifts due to the poly(A) tracts in these regions are found in MSI+ tumors.

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

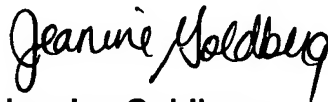
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272- 0745.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

A handwritten signature in black ink that reads "Jeanine Goldberg". The signature is written in a cursive, flowing style.

Jeanine Goldberg

Patent Examiner

January 7, 2005